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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/495,823 01/31/00 GLUKSMANN

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000826 HM22/0927  
ALSTON & BIRD LLP  
BANK OF AMERICA PLAZA  
101 SOUTH TRYON STREET, SUITE 4000  
CHARLOTTE NC 28280-4000

EXAMINER

PAK, Y

ART UNIT

PAPER NUMBER

1652

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DATE MAILED:

09/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/495,823

Applicant(s)

GLUKSMANN ET AL.

Examiner

Yong Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 243-268 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 243-268 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____    | 6) <input type="checkbox"/> Other:  |

### **DETAILED ACTION**

The preliminary amendment filed on June 7, 2000, canceling claims 1-242 and addition of claims 243-268, has been entered.

Claims 243-268 are pending.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 243-249 and 254-255 drawn to DNA encoding a sulfatase, host cell containing said DNA and a method of producing the protein, classified in class 435, subclass 193.
- II. Claims 250-252, drawn to sulfatase and a pharmaceutical composition containing said sulfatase, classified in class 424, subclass 94.5.
- III. Claims 253, drawn to antibody against sulfatase, classified in class 530, subclass 387.9.
- IV. Claims 256-258, drawn to a method for detecting the sulfatase and a kit, classified in class 435, subclass 15.
- V. Claims 259-261, drawn to a method for detecting the DNA encoding sulfatase and a kit, classified in class 435, subclass 6.
- VI. Claims 262-263, drawn to a method for identifying a compound binding to the sulfatase, classified in class 514, subclass 789.
- VII. Claim 264, drawn to a method for modulating the activity of the sulfatase and classified in class 435, subclass 325.

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- VIII. Claim 265, drawn to a method for identifying a compound that modulates the activity of the sulfatase classified in class 435, subclass 15.
- IX. Claim 266, drawn to a method for identifying an agent that modulates the expression of the DNA of Invention I, classified in class 435, subclass 325.
- X. Claim 267, drawn to a method for modulating the level of expression of the DNA of Invention I with an agent, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

In addition to the patentably distinct inventions mentioned above, sulfatase of SEQ ID NO:1, 3, 5 and 7 encoded by the DNA of SEQ ID NO:2, 4, 6 and 8, respectively, are patentably distinct inventions for the following reasons. DNA of SEQ ID NO:2, 4, 6 and 8 are patentably distinct as encoding enzymes with different structures, functions, substrate specificities, and utilities. The protein of SEQ ID NO:1, 3, 5 and 7 are patentably distinct as having different structures, functions, substrate specificities, and utilities.

Therefore, in addition to electing one of the groups of Inventions I-X, applicants are required to further elect one sulfatase of SEQ ID NO:1, 3, 5 or 7 or one DNA of SEQ ID NO:2, 4, 6 or 8.

Inventions I-III are patentably distinct because a DNA, a protein and an antibody, are different compounds, each with its own chemical structure and function, and they have different utilities. The DNA molecule of Inventions I is not limited in use to the production of polypeptide of Invention II and can be used as a hybridization probe, and protein of Invention II can be obtained by a materially different method such as by

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biochemical purification. The structure of an antibody of Invention III is not predictable from the structure of the protein of Invention II and an antibody can cross-react with various proteins.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA of Invention I can be used for the production of the protein of Invention II.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Invention II can be used for the production of the antibody of Invention III.

The methods of Inventions IV-X are patentably distinct as directed to materially different methods employing different products. Invention IX uses a polypeptide, Invention V uses DNA, Invention VI-VII uses a cell or a cell expressing a polypeptide and a test compound, Invention VIII uses a polypeptide and a compound, Invention IX uses a DNA and a compound and Invention X uses a cell expressing a DNA and a compound. In addition, the methods of Inventions IV-X have different effects and utilities.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***


Drawings filed concurrently with the application has been objected by the Draftsman. Please refer to the attached PTO-948 form for details.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3173.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak  
Patent Examiner

  
PONNATHAPUACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

September 26, 2001